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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,020	GANGOLLI	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 38, 41 drawn to an isolated polypeptide comprising the amino acid sequence selected from the group consisting of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34; variants, allelic variants, wherein the said allelic variant comprises an amino acid sequence encoded by the nucleic acid sequence selected from the group consisting of SEQ ID NOs: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35; a pharmaceutical composition; a kit comprising the pharmaceutical composition; variants of SEQ ID NO: 211; classified in class 530, subclass 350; class 514, subclass 2.

Should Group I be elected, applicants are required to select one amino acid sequence from claim 1, each items a-d, claim 2 and select one nucleic acid sequence from claim 3.

II. Claims 5-14, 39, 42 drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence encoding a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, wherein the nucleic acid sequence differs by a single nucleotide from a nucleic acid sequence selected from the group consisting of SEQ ID NOs: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35; variants, fragments and complements thereof; vectors; cells; a pharmaceutical composition; a kit comprising the pharmaceutical composition; classified in class 435, subclass 69.1, 320.1, 252.3; class 536, subclass 23.5

Should Group II be elected, applicants are required to select one amino acid sequence from claim 5, each items a-e, and select one nucleic acid sequence from claims 8, 9 (items a and b) and 10.

III. Claims 15-17, 40 and 43, drawn to an antibody that selectively binds to the polypeptide of claim 1, wherein the antibody is a monoclonal antibody; a pharmaceutical composition; a kit comprising the pharmaceutical composition ; classified in class 530, subclass 387.1+.

Should Group III be elected, applicants are required to select one amino acid sequence from claim 1.

IV. Claims 18, drawn to a method determining the presence of a polypeptide of claim 1 by using an antibody that binds immunospecifically to the polypeptide; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group IV be elected, applicants are required to select one amino acid sequence from claim 1.

V. Claim 19, 20 and 21 drawn to a method for detecting the presence of a nucleic acid molecule of claim 5 in a sample by contacting the sample with a nucleic acid probe that binds to said nucleic acid molecule, wherein the nucleic acid is used as marker for cancerous cell or tissue type; classified in class 536, subclass 23.1, 24.3, 24.31; class 435, subclass 6.

Should Group V be elected, applicants are required to select one amino acid sequence encoded by a nucleic acid sequence from claim 5.

VI. Claim 22 and 23, drawn to a method of identifying an agent that binds to a polypeptide of claim 1 by contacting said polypeptide with said agent, wherein the agent is a cellular receptor or a downstream effector; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group VI be elected, applicants are required to select one amino acid sequence from claim 1.

VII. Claims 24 and 25, drawn to the use of an agent that modulates the expression or

activity of a polypeptide of claim 1 by contacting a cell expressing the polypeptide with said agent, or contacting a cell expressing the polypeptide with a compound that binds to said polypeptide in an amount sufficient to modulate the activity of the polypeptide; classified in class 530, subclass 350, 300; class 435, subclass 7.1, 69.1.

Should Group VII be elected, applicants are required to select one amino acid sequence from claim 1.

VIII. Claims 26, 27, 28 and 29, drawn to a method of treating or preventing a NOVX-associated disorder by administering to a subject the polypeptide of claim 1, wherein the disorder is selected from the group consisting of cardiomyopathy and atherosclerosis and the disorder is related to cell signal processing and metabolic pathway modulation, wherein said subject is a human; classified in class 530, subclass 350, 300; class 514, subclass 2.

Should Group VIII be elected, applicants are required to select one amino acid sequence from claim 1.

IX. Claims 30, 31, 32 and 33, drawn to a method of treating or preventing a NOVX-associated disorder by administering to a subject the nucleic acid of claim 5, wherein the disorder is selected from the group consisting of cardiomyopathy and atherosclerosis and the disorder is related to cell signal processing and metabolic pathway modulation, wherein said subject is a human; classified in class 536, subclass 23.5; class 514, subclass 44.

Should Group IX be elected, applicants are required to select one amino acid sequence encoded by a nucleic acid sequence from claim 5 and select nucleic acid from claim 35.

X. Claims 34, 35, 36 and 37, drawn to a method of treating or preventing a NOVX-associated disorder by administering the antibody of claim 15, wherein the disorder is diabetes and the disorder is related to cell signal processing and

metabolic pathway modulation, wherein said subject is a human; classified in class 530, subclass 350, 300; class 424, subclass 130.1+

Should Group X be elected, applicants are required to select one amino acid sequence from claim 1.

XI. Claim 44 and 45, drawn to a method for determining the presence of or predisposition to a disease associated with altered levels of the polypeptide of claim 1 in a mammal subject, wherein the predisposition is to a cancer; classified in class 530, subclass 350, 300; class 435, subclass 69.1, 7.1

Should Group XI be elected, applicants are required to select one amino acid sequence from claim 1.

XII. Claims 46 and 47, drawn to a method for determining the presence of or predisposition to a disease associated with altered levels of the nucleic acid of claim 5 in a mammal subject, wherein the predisposition is to a cancer; classified in class 536, subclass 23.5; class 435, subclass 6.

Should Group XII be elected, applicants are required to select one amino acid sequence encoded by a nucleic acid sequence from claim 5.

XIII. Claim 48, drawn to a method of treating a pathological state in a mammal by administering to the mammal a polypeptide in an amount that is sufficient to alleviate the pathological state, wherein the polypeptide is having an amino acid sequence at least 95% identical to a polypeptide comprising an amino acid sequence of at least one of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34 or a fragment thereof; classified in class 530, subclass 350, 300; class 514, subclass 2.

Should Group XIII be elected, applicants are required to select one amino acid sequence.

XIV. Claim 49, drawn to a method of treating a pathological state in a mammal by

administering to the mammal an antibody of claim 15 in an amount that is sufficient to alleviate the pathological state; classified in class 530, subclass 387.1+; class 424, subclass 130.1+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the protein product of Invention I can be made by another materially distinct processes, such as purification from the natural source or by chemical synthesis. Therefore, the inventions are distinct.

The polypeptide of group I is related to the antibody of group III as being the antigen for the antibody. Although the protein and antibody are related, they are distinct inventions. The protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify a receptor. Further, the protein of Group I and the antibody of group III are structurally and functionally distinct molecules with different amino acids and different sequences.

Inventions I and IV/V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of group I is not necessary for the practice of invention of IV and V. Therefore the inventions are distinct.

Invention I is related to inventions VI, VII, VIII, XI, and XIII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II has

demonstrated different processes of use as set forth in the claims of Groups VI, VII, VIII, XI, and XIII.

Inventions I and IX, X, XII and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of group I is not necessary for the practice of invention of IX, X, XII and XIV. Therefore the inventions are distinct.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of group II is a separate and distinct chemical entity from the antibody of group III. The nucleic acid of Group II does not encode the antibody of Group III and is not used for the practice of Group III. Therefore the inventions are distinct.

Invention II is unrelated to inventions IV, VI, VII, VIII, X, XI, XIII and XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of Group II is not used for the practice of the methods of groups IV, VI, VII, VIII, X, XI, XIII and XIV. Therefore the inventions are distinct.

Inventions II and inventions V, IX and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group II can be used on another, materially distinct process, such as recombinant production of protein.

Inventions III and inventions IV, V, VI, VII, VIII, IX, XI, XII and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of III is not necessary for the

practice of inventions of IV, V, VI, VII, VIII, IX, XI, XII and XIII. Therefore inventions are distinct.

Invention III is related to inventions X and XIV as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of group III can be used on another, materially distinct process, such as affinity chromatography.

Invention IV and inventions V, VI, VII, VIII, IX, X, XI, XII, XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of IV is not necessary for the practice of inventions V, VI, VII, VIII, IX, X, XI, XII, XIII. Therefore the inventions are distinct.

The inventions IV, X and XIV are related by virtue of the antibody which is used in the methods. The inventions are distinct, each from the other, because they require different steps and are directed to different ends and different effect. Therefore the inventions are distinct.

Inventions V and inventions VI, VII, VIII, X, XI, XIII, XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of V is not necessary for the practice of inventions VI, VII, VIII, X, XI, XIII, XIV. Therefore the inventions are distinct.

Inventions V, IX and XII are related by virtue of the nucleic acid which is used in the methods. The inventions are distinct, each from the other, because they require different steps and are directed to different ends and different effect. Therefore the inventions are distinct.

Inventions VI, VII, VIII, XI and XIII are related by virtue of the polypeptide, which is used in the methods. The inventions are distinct, each from the other, because they require different steps and are directed to different ends and different effect. Therefore the inventions are distinct.

Inventions VI and inventions IX, X, XI, XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of VI is not necessary for the practice of inventions IX, X, XI, XIV. Therefore the inventions are distinct.

The restriction requires for a selection of a single sequence of polynucleotide sequence and a single sequence of amino acid sequence because each sequence has a different chemical and physical property (See specification pages 10+ and Table A). For example the NOV1 nucleic acid molecule has the nucleotide sequence shown in SEQ ID NO: 1; and the NOV1 protein has amino acid sequences of SEQ ID NO: 2 (Table A) which is homologous to an EGF related SCUBE1-like family protein (page 10); while NOV2 nucleic acid molecule has the nucleotide sequence shown in SEQ ID NO: 5; and the NOV2 protein has amino acid sequences of SEQ ID NO: 6 (Table A), which is homologous to the adipocyte complement C1q Tumor Necrosis Factor like family of proteins (page 11). In addition the invention also includes NOV3 to NOV11, which have different nucleic acid and amino acid sequences (see Table A), which are distinct from each other. Therefore, the use of each sequence in the method claims would have a different effect, for example use of a nucleic acid sequence from NOV1 as a probe for the detection of nucleic acid in a sample may not detect the nucleic acid sequence of NOV2, while use of a polypeptide sequence of NOV1 for identifying a compound that specifically binds to the polypeptide of NOV1 may not detect the compounds that bind with the polypeptide of NOV2. Therefore each sequence is distinct from the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Attorney Ivor Elriffi on January 28, 2004, to request an oral election to the above restriction requirement, but did not result in an election being made.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (571) 272-0951. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Rita Mitra, Ph.D.
April 17, 2004